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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/574,342	03/30/2006	Eric Jonsen	US030295US	8861

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PHILIPS INTELLECTUAL PROPERTY & STANDARDS
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EXAMINER	
PATEL, NATASHA	
ART UNIT	PAPER NUMBER
3766	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/29/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/574,342	JONSEN, ERIC	
	Examiner	Art Unit	
	Natasha N. Patel	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 March 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *30 March 2006* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *30 March 2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Drawings

1. The drawings are objected to because the details of Figures 2 and 5 are not indicated. It is suggested that the elements of the schematics be labeled to provide a more useful drawing. For example, in Figure 2, element 12 can be labeled "electrode" and element 200 can be labeled "defibrillator." Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

2. The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use. It is suggested that the headings be included to differentiate between the sections.

Arrangement of the Specification

3. As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

(a) TITLE OF THE INVENTION.
(b) CROSS-REFERENCE TO RELATED APPLICATIONS.
(c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
(d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT.
(e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC.
(f) BACKGROUND OF THE INVENTION.
    (1) Field of the Invention.
    (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
(g) BRIEF SUMMARY OF THE INVENTION.
(h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
(i) DETAILED DESCRIPTION OF THE INVENTION.
(j) CLAIM OR CLAIMS (commencing on a separate sheet).
(k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
(l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-8, 10-12, and 14-16 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Freeman et al. (US Patent 5,462,157).

6. Regarding Claims 1 and 14, Freeman discloses an enclosure for a medical electrode (see envelope enclosing first compartment 94; col. 1, lines 32-35 and Figure 3), which seals the electrode against moisture loss while the electrode remains in electrical communication with a medical instrument (see col. 2, lines 22-25) comprising:

an enclosure formed of flexible material which is adapted to be sealed against moisture loss (see col. 1, lines 28-36); The examiner considers that the envelope is made of a flexible material because it is able to be folded over (see col. 1, lines 62-65) and because a reinforcing layer needs to be added to it to provide structural rigidity (see col. 2, lines 6-8). If the envelope were already rigid, a reinforcing layer would be unnecessary.

an interior connector (see terminals 26 and 28, Figure 1) located on the interior of the enclosure (defined by the area enclosed by adhesive strip 15) and adapted to connect to a medical electrode (see Figure 1; col. 3, lines 51-56); and

an exterior connector (see connector 24 or 66 or 116) located on the outside of the enclosure (see Figures 1 and 3) and adapted to connect to a medical instrument (see col. 2, lines 22-30), the exterior connector being in electrical communication with the interior connector (see col. 4, line 65- col. 5, line 4; Figure 5).

7. Regarding Claim 2, Freeman discloses a medical electrode (see electrodes 16 and 18 or electrodes 56 and 58 or electrodes 106 and 108) having a wireset (see wires 20 and 22 or wires 62 and 64 or wires 112 and 114) coupled to the interior connector (see terminals 26 and 28), wherein the medical electrode is sealed inside of the enclosure (see col. 7, lines 36-39). The examiner considers that although, terminal connections are not shown in Figures 3 and 5, terminals similar to the ones shown in Figure 1 are present because the wires must be connected to the electrodes in some manner.

8. Regarding Claim 3, see rejection of similarly worded Claim 2 above. In addition, Freeman discloses a medical instrument coupled in electrical communication with the exterior connector (see col. 2, lines 22-30).

9. Regarding Claim 4, see rejection of similarly worded Claim 1 above. The examiner considers that since the entire envelope is flexible, then a wall of flexible material necessarily exists. Furthermore, Freeman discloses that the interior and exterior connectors are sealed through a hole (see hole formed by arcuate upper and lower surfaces 90 and 92, Figure 4; col. 2, lines 39-43) in the wall of flexible material (see Figure 3 and col. 4, lines 26-30).

10. Regarding Claim 5, Freeman discloses a flange (see gasket 88) having the interior and exterior connectors located on opposite sides thereof (see Figure 3), wherein the flange is sealed to a hole in the wall of flexible material (see col. 4, lines 31-41). The examiner considers that the gasket is a flange because a flange is a ring or collar, usually provided with holes for bolts, and screwed or welded over the end of a

tube or pipe to permit other objects to be attached to it (*Random House Unabridged Dictionary, © Random House, Inc. 2006*).

11. Regarding Claim 6, Freeman further discloses that the flange is heat-sealed to the periphery of a hole in the wall of flexible material (see col. 2, lines 39-43; col. 4, lines 23-25).

12. Regarding Claims 7 and 8, Freeman discloses that the flange is formed of a rigid insulative, heat sealable material (see RTV; col. 4, lines 26-28).

13. Regarding Claim 10, Freeman discloses wherein the medical instrument comprises an external defibrillator (see col. 1, lines 20-25).

14. Regarding Claim 11, Freeman discloses the enclosure flexible material comprises a hermetically sealable pouch for storing the electrode (see col. 1, lines 50-54 and lines 62-65). The examiner considers that the folding and sealing of the single sheet of flexible material forms an envelope, which is in other words, a pouch.

15. Regarding Claim 12, Freeman discloses that the interior connector (terminals 26 and 28) and the exterior connector (connector 24) comprise an electrical connector (wires 20 and 22) having the first end disposed in the interior of the enclosure, and a second end disposed on the exterior of the enclosure (see Figure 1).

16. Regarding Claim 15, Freeman discloses sealing the enclosure comprises heat-sealing the enclosure (see col. 4, lines 58-62; Figure 5).

17. Regarding Claim 16, see rejections of similarly worded Claims 6 and 7 above.

Claim Rejections - 35 USC § 103

18. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> **(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.**

19. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Freeman et al. (US Patent 5,462,157) in view of Stolte (US Patent 5,697,955).

20. Regarding Claim 9, Freeman discloses detaching the electrode from the interior surface of the package (see col. 1, lines 40-43 and col. 3, lines 1-3). Freeman also discloses the interior connector is in electrical communication with the exterior connector, and the exterior connector is detachably connected to the signal path of a medical instrument (see Figure 1 and col. 2, lines 25-27). Freeman does not disclose that the electrode is detachably connected to the interior connector. Stolte discloses a similar electrode package wherein the electrode is detachably connected to the interior connector (see col. 7, lines 38-45), wherein the medical instrument is adapted to monitor the functioning of the electrode via the signal path (see col. 6, lines 53-58; col. 9, lines 4-7; col. 11, lines 41-47). It would have been obvious to one of ordinary skill in the art at the time of the invention to include the monitoring of the functioning of the electrode into Freeman's invention because Stolte teaches that doing so can indicate the presence or lack of electrodes in the package as well as the freshness of the electrodes (see col. 2, lines 1-3 and 32-38).

21. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Freeman et al. (US Patent 5,462,157).

22. Regarding Claim 13, Freeman does not disclose that the medical instrument further comprises an electrical plug adapted to connect to the exterior connector. Instead, Freeman discloses that the exterior connector is an electrical plug (see Figure 1). It would have been obvious to one of ordinary skill in the art at the time of the invention to switch the plug from being on the exterior connector to being on the medical instrument because the Applicant has not disclosed any criticality to placing the plug on the medical instrument as opposed to placing the plug on the exterior connector. Furthermore, one of ordinary skill in the art would have expected Freeman's invention to perform equally well if the medical instrument had either a plug or an outlet as long as the exterior connector was similarly changed to the opposite component because all that is necessary is an electrical connection to be made so energy can be delivered from the medical device to the electrode package. Thus, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Freeman's invention to obtain the invention as specified in Claim 13 because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art of Nash.

Conclusion

23. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natasha N. Patel whose telephone number is 571-272-5818. The examiner can normally be reached on M-F 8:30-5:00.

24. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on 571-272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

25. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NNP
1/18/07

Robert E. Pezzuto
Supervisory Patent Examiner
Art Unit 3766